UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA	)	**FILED UNDER SEAL**
v.	)	**No. 10-cr-694-RWT**
LAUREN STEVENS,	)	
Defendant.	)	

DEFENDANT'S OPPOSITION TO UNITED STATES' MOTION IN LIMINE REGARDING OPINION TESTIMONY

Defendant Lauren Stevens, through counsel, respectfully opposes the United States' Motion in Limine Regarding Opinion Testimony (Doc. #36). Through its motion, the government seeks to preclude any attorney witnesses from stating their views or opinions about the truthfulness or propriety of the Company's responses to the FDA unless those opinions were expressed to Ms. Stevens at the time, and further seeks at the outset to prevent any non-expert attorney witnesses from expressing any opinions at all.

The Court should deny the government's motion because it is premature. The relevance and propriety of witness testimony is fact-intensive and must be decided case-by-case, based on the particular testimony offered in the context of the facts established at trial. No decision of the issues presented by the government's motion is possible until the Court has before it, in context, the substance of the testimony at issue.

Although the government's motion in limine is premature, the government is incorrect regarding both the relevance of anticipated defense witness testimony and the propriety of lay opinion testimony under Rule 701. Defense witness testimony regarding GSK's responses to the FDA will go to core issues in dispute under the Indictment, the relevant law, and the government's own contentions. Moreover, contrary to the government's argument, testimony by fact

witnesses regarding inferences and opinion, when based on the witness's own perceptions as a fact witness, may be proper as provided by Rule 701. Finally, the principles regarding lay opinion testimony under Rule 701 apply evenhandedly. The government, which presumably will offer witness testimony to try to show that disputed statements were false or misleading, and were knowingly, willfully, and/or corruptly made, may not preclude the defense from offering contrary proof.

BACKGROUND

The Indictment charges Lauren Stevens with obstruction of justice, concealment of documents, and making false statements, in connection with Ms. Stevens' involvement in responding to a United States Food and Drug Administration ("FDA") inquiry to GlaxoSmithKline ("GSK" or the "Company") regarding possible off-label marketing of GSK's antidepressant product Wellbutrin SR ("Wellbutrin"). Ms. Stevens, then a GSK Vice President and Associate General Counsel, headed GSK's team of in-house and outside counsel that responded to the FDA's inquiry, and signed GSK's response letters to the FDA.

In October 2002, the FDA requested information from GSK about the marketing of Wellbutrin, expressing concern that GSK might be promoting the off-label use of Wellbutrin for weight loss.[1] Ms. Stevens led the team tasked with responding to the FDA's request.[2] That team included other GSK in-house attorneys (including a former FDA Associate General Counsel), and the law firm of King & Spalding LLP.[3] The lead King & Spalding attorney was a former FDA Associate Chief Counsel who had served as one of the agency's chief litigators of

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[1] Ind. ¶ 3; Decl. of Brien T. O'Connor ¶ 6 ("O'Connor Decl.") (Doc. #25-2, attached hereto as Ex. 1).

[2] Ind. ¶ 4; O'Connor Decl. ¶ 8.

[3] O'Connor Decl. ¶¶ 8-11; *see* Gov. Mot. at 3 (acknowledging that Ms. Stevens, "in responding to the FDA, worked with both in-house attorneys at GSK and some outside counsel").

both civil and criminal pharmaceutical cases.[4]

King & Spalding attorneys were intimately involved in investigating the facts, collecting documents, and preparing GSK's response. GSK and King & Spalding conducted an extensive review of GSK promotional materials, speaker training slides, and other documents relating to Wellbutrin. King & Spalding interviewed over a dozen GSK employees involved in the marketing of Wellbutrin, as well as the three doctors whom the FDA identified as potentially involved in off-label promotion. On the basis of this review, King & Spalding concluded that GSK did not have a corporate strategy to promote Wellbutrin to achieve weight loss or to treat obesity.[5]

GSK sent six substantive response letters to the FDA between December 2002 and November 2003. The letters addressed the FDA's major areas of inquiry and described, in narrative format, GSK's promotional program for Wellbutrin. The letters also disclosed several instances of noncompliance with corporate policies regarding the marketing of Wellbutrin that GSK and King & Spalding uncovered during the investigation. King & Spalding attorneys drafted, edited, and reviewed each of GSK's substantive response letters to the FDA.[6] In each case, the letters were sent to the FDA only after a consensus was reached among the various attorneys on the response team regarding the Company's response.

The core conclusion of the GSK and King & Spalding team was that, while certain physician speakers may have violated Company policy by making statements concerning Wellbutrin and weight loss, GSK did not have a centralized corporate strategy to promote Wellbutrin off-label as a means of treating obesity.[7] Based on this conclusion, GSK stated in a February 28, 2003 letter to the FDA:

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[4] O'Connor Decl. ¶ 10.
[5] *Id.* ¶ 13.
[6] *Id.* ¶ 14.
[7] *Id.* ¶¶ 13, 18.

a. GSK has not developed, devised, established or maintained any program or activity to promote or encourage, either directly or indirectly, the use of Wellbutrin SR as a means to achieve weight loss or treat obesity. . . . GSK's promotional material and activities for Wellbutrin SR are consistent with the approved Prescribing Information and supporting clinical data.

b. GSK has not developed or maintained promotional plans or activities to directly or indirectly promote Wellbutrin SR for weight loss or the treatment of obesity.[8]

The Indictment alleges Ms. Stevens made these and similar statements knowing they were false.[9]

GSK also voluntarily produced documents and other information requested by the FDA.[10] Early in the investigation, GSK informed the FDA that the Company would make a good-faith effort to obtain from physicians under contract with GSK materials presented by physician speakers at GSK-sponsored promotional programs.[11] Accordingly, the response team sent out requests to over 500 physicians, 40 of whom sent copies of their presentations to GSK. GSK forwarded all of the materials received from the physicians to counsel at King & Spalding, who in turn reviewed the presentations to determine whether there was any off-label promotion. King & Spalding concluded that while some of the presentation slides did contain potentially off-label content, it was impossible without extensive interviews of doctors to determine how or if the presentations had been used and what the physicians actually said during their presentations.[12]

Concerned that simply producing the presentations with no explanation could create a misleading impression, the GSK and King & Spalding team subsequently discussed at length whether to produce the presentations to the FDA absent the context necessary to fairly assess the

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[8] *Id.* ¶ 17.

[9] *See* Ind. ¶¶ 28-41.

[10] O'Connor Decl. ¶¶ 12-13.

[11] *Id.* ¶ 20.

[12] *Id.* ¶¶ 21-22

presentations.[13] The team reached a consensus decision not to produce the presentations immediately, but instead to seek a meeting with the FDA at which GSK would discuss the presentations.[14] In this regard, Ms. Stevens called the FDA several times in May/June 2003 to schedule such a meeting. However, the FDA did not respond positively to Ms. Stevens' calls, and the anticipated meeting never occurred.[15] At no time did King & Spalding advise GSK or Ms. Stevens that failure to produce the presentations at that time was unlawful.[16] The Indictment alleges that Ms. Stevens' failure to make the voluntary production of the presentations constituted obstruction and an illegal concealment of documents.[17]

ARGUMENT

I. The Government's Motion is Premature

The government's motion to exclude the personal views or opinions of defense witnesses is premature, because none of the testimony at issue has been proffered, and any determination of admissibility requires an individualized assessment. The government admits at the outset that it does not know what opinion testimony the defense will put on, and hence what testimony the government is trying to exclude. Gov. Mot. at 3.

An assessment of whether a witness may offer opinion testimony under Rule 701 is a case-by-case determination that necessarily requires examination of the specific testimony and witnesses in question. *See United States v. Smith*, 591 F.3d 974, 983 (8th Cir. 2010) (noting that Rule 701 "inquiry requires a case-by-case analysis of both the witness and the witnesses' opinion"); *United States v. Beck*, 418 F.3d 1008, 1015 n.4 (9th Cir. Or. 2005) (taking a "a case-by-

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[13] *Id.* ¶ 23; Ind. ¶ 34.
[14] O'Connor Decl. ¶ 23.
[15] *Id.*¶ 24.
[16] *Id.*¶ 23.
[17] *See* Ind. ¶¶ 12-25, 34-41.

case approach in deciding whether a lay opinion witness had sufficient contact with the defendant to render the witness's testimony helpful within the meaning of Rule 701"); *Cobb v. Knode*, No. CIV. 09-4110, 2010 U.S. Dist. LEXIS 94174, at *21 (D.S.D. Sept. 8, 2010) ("The inquiry is properly analyzed on a case-by case basis, examining both the witness and the opinion."); *see also United States v. Roe*, 606 F.3d 180, 185 (4th Cir. 2010) (quoting *United States v. Perkins*, 470 F.3d 150, 155 (4th Cir. 2006)) (recognizing that the line between lay and expert opinion testimony can sometimes be "a fine one" and "not easy to draw").

As the government concedes in its motion (at 3), the testimony targeted by the government has not been sufficiently developed to permit a full and fair adjudication of admissibility as to specific testimony. *See In re Parmalat Sec. Litig.*, 477 F. Supp. 2d 637, 642 (S.D.N.Y. 2007) (holding that motion in limine regarding lay opinion testimony under Rule 701 was premature where the exact testimony in question was unclear); *EEOC v. Schott N. Am., Inc.*, No. 06cv1246, 2009 U.S. Dist. LEXIS 8546, at *7-10 (M.D. Pa. Feb. 5, 2009) (denying as premature a motion in limine to exclude lay opinion testimony because the court could not "anticipate the exact contents of the testimony at this time").

None of the government's cases are to the contrary. All but one of the cases cited by the government involved a ruling at trial, at or near the time the testimony was being offered.[18] In the one cited case where a court made a blanket ruling before the defense's presentation of its case, as the government requests here, the appellate court held the district court abused its discretion by excluding the attorney witness testimony, where the attorney was offered not as an expert

[18] *See United States v. Stadtmauer*, 620 F.3d 238, 262 (3d Cir. 2010); *United States v. Wantuch*, 525 F.3d 505, 514 (7th Cir. 2008); *United States v. Henke*, 222 F.3d 633, 641-642 (9th Cir. 2000); *United States v. Nash*, 175 F.3d 429, 435 (6th Cir. 1999); *United States v. Newman*, 49 F.3d 1, 7 (1st Cir. 1995); *United States v. Rea*, 958 F.2d 1206, 1214 (2d Cir. 1992); *Torres v. County of Oakland*, 758 F.2d 147, 150 (9th Cir. 1985); *United States v. Eckman*, 656 F.2d 308, 311-314 (8th Cir. 1981).

but as a witness to the facts of the case. *See Gomez v. Rivera Rodriguez*, 344 F.3d 103, 113, 114-115 (1st Cir. 2003).

Accordingly, the government's blanket request to exclude all opinion testimony from the attorney witnesses is highly premature.

II. Attorney Witnesses' Views and Opinions Regarding Statements or Decisions in Responding to the FDA's Inquiry May be Relevant

The government contends that no view or opinion held by any defense witness could possibly be relevant to any "fact of consequence" in this prosecution unless that view or opinion was communicated to Ms. Stevens at the relevant time. Mot. at 3-4. As noted, the relevance of any particular testimony cannot be evaluated without knowing the testimony's content and foundation, as well as the context established by the government's contentions, the other evidence elicited, and the purpose for which the defense offers the testimony. Contrary to the government's contention, however, a given witness's view of GSK's actions and statements in response to the FDA's inquiry may be highly relevant for a number of reasons.

The government's relevancy argument (Gov. Mot. at 3-4) is directed only to the anticipated assertion that Ms. Stevens relied on the advice of counsel in developing and submitting GSK's responses. Thus, the government's one-sentence contention that "[u]nless the witness expressed the particular opinion at issue to the defendant at the time, however, such opinion testimony is not relevant" (Mot. at 4)—is directed solely at the issue of Ms. Stevens' state of mind. The government ignores a host of other issues to which the views of those who participated in crafting GSK's responses may be relevant.

First, the testimony of those involved in developing GSK's responses may be highly relevant regarding the core allegation in this prosecution—that the responses were false or misleading. *See* Ind. ¶¶ 28-31, 32-33, 37, 40-41; Ind. at 11, 12, 13, 15, 16, 18. The evidence will show

that the letters were drafted by attorneys on GSK's response team, circulated among the team for review, comments, and revision, and finalized based upon team consensus before submission. Testimony by the individuals who investigated, drafted, revised, commented on, and approved of the statements in the letters are likely to be highly relevant to determining whether the representations in the statements were true or false, misleading or not.[19]

Second, the testimony of GSK's in-house and outside counsel may be relevant to the statutory defense in 18 U.S.C. § 1515(c), which provides that Chapter 73 of Title 18, covering Obstruction of Justice, "does not prohibit or punish the providing of lawful, bona fide, legal representation services in connection with or anticipation of an official proceeding." It is undisputed that Ms. Stevens, GSK's Associate General Counsel, was providing legal representation to GSK in responding to the FDA's inquiry in this case. Thus, she may not be convicted of obstruction of justice under § 1512(c), or falsification of records under § 1519, unless the government proves her legal representation was not lawful or bona fide. The views, opinions or testimony of qualified attorneys on GSK's response team who conducted GSK's investigation and crafted its response letters may be relevant to whether the development and submission of those letters was part of a lawful and bona fide legal representation.

Third, the government's motion would create a blanket prohibition on any attorney witness testifying as to "their own good faith" in putting together GSK's responses to the FDA's requests. Mot. at 4. The government itself, however, elsewhere has made the views and the good faith of the attorney witnesses relevant to any asserted advice-of-counsel defense. In its

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[19] The government's motion specifically would prohibit a witness from stating "whether, at the time GSK was responding to the FDA on the Wellbutrin issue, the witnesses viewed GSK's responses to the FDA as appropriate or fair and not false and misleading." Mot. at 3-4.

Strikingly, the government does not state whether the same rule it proposes here would also apply to government witnesses: *i.e.*, that no government witness would be allowed to state his view that the statements in question were false or misleading.

motion to preclude the advice of counsel defense, the government has asserted that the defense is "*not available where the counsel participates in the crime*."[20] The government thus takes the position that "the defense is not available if the evidence shows that some other counsel agreed with Stevens to conceal the 'incriminating' documents and information from the FDA ...."[21] By arguing that unnamed attorneys on GSK's response team may have been complicit in criminal wrongdoing, and that the availability of a legal defense turns on those unnamed counsel's criminal complicity, the government has made the state of mind of any attorney on whose advice Ms. Stevens relied a relevant issue.

Finally, testimony of other attorneys based on their first-hand participation in developing GSK's responses may be relevant to Ms. Stevens' state of mind, even if counsel's views were not expressed directly to Ms. Stevens at the time. Ms. Stevens certainly may have relied on the views or advice of counsel even if those views were communicated to her circumstantially or indirectly or through others. Ms. Stevens, for example, may have relied, as she would have been entitled to, on implicit approval gained by acceptance of revisions made to multiple rounds of drafts, or the absence of objection when an intention to submit a final draft ultimately was declared, just as much as she may have relied on explicit statements directed to her. Counsel's views developed during their investigation, and their views regarding the draft and final response letters, may be relevant to the body of legal advice on which Ms. Stevens relied.

Thus, while any specific relevancy determination is premature, the views and lay opinions of attorneys on GSK's response team potentially may be relevant to a variety issues at trial.

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[20] United States' Motion to Preclude Advice of Counsel Defense to 18 U.S.C. § 1519 and For Hearing Regarding Applicability of the Defense to Other Charges, at 17 (emphasis added) (Doc. # 19).

[21] *Id.*

Whether such potentially relevant views or opinions are admissible will in turn depend on whether they satisfy the criteria of Rule 701 (discussed in the following section).

III. Lay Opinion Testimony By Fact Witnesses May Be Proper Under Rule 701

"A lay witness in a federal court proceeding is permitted under Federal Rule of Evidence 701 to offer an opinion on the basis of relevant historical or narrative facts that the witness has perceived." *MCI Telecomm. Corp. v. Wanzer*, 897 F.2d 703, 706 (4th Cir. 1990) (citation omitted). Though lay opinion testimony was once disfavored, "[t]he modern trend favors the admission of opinion testimony, provided that it is well founded on personal knowledge [as distinguished from hypothetical facts] and susceptible to specific cross-examination." *Id.* (quoting *Teen-Ed, Inc. v. Kimball International, Inc.*, 620 F.2d 399, 403 (3d Cir. 1980); 3 J. Weinstein, *Evidence* ¶ 701[02] at 701-09 and 707-17 (1978)) (alteration in original). If attorney witness testimony in this case is based on the witnesses' perceptions and personal knowledge gained from their participation in the factual events in this case, it may be admissible. *See Smithers v. C & G Custom Module Hauling*, 172 F. Supp. 2d 765, 776 (E.D. Va. 2000) ("to be admissible under Fed. R. Evid. 701, the proposed testimony need only be based on an observation that the witness made that serves to explain the witness' testimony or is otherwise probative of a fact in issue") (citing *Mattison v. Dallas Carrier Corp.*, 947 F.2d 95, 110 (4th Cir. 1991)).[22]

To be admissible, opinion testimony by a fact witness must be "(a) rationally based on the perception of the witness, (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue, and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702." Fed. R. Evid. 701. Any views or opinions expressed

[22] *Accord In Re Air Crash at Little Rock Ark.*, 291 F.3d 503, 515-16 (8th Cir. 2002) (citations omitted) ("Personal knowledge or perceptions based on experience is a sufficient foundation for such testimony. Lay opinion testimony is admissible if an analysis of the events, in the form of an opinion, is necessary.").

by defense witnesses who participated in developing GSK's responses to the FDA will be based on their perceptions from that first-hand experience. Whether the specific testimony is helpful to a clear understanding of the witness's testimony, or to the determination of a fact in issue, must be determined once the witness's potential testimony is before the Court. Similarly, whether a witness is qualified to offer an opinion is based on his first-hand experience with the facts of the case, rather than his specialized knowledge, must be determined based on the witness's actual testimony in context.

The government tries to pretermit this analysis by suggesting that "if the jury already has all of the information upon which the witness's opinion is based, the opinion would not be helpful" to the jury's understanding. Mot. at 4. This argument thus effectively seeks to reduce Rule 701 to a tautology that would never allow lay opinion testimony. Like the other points of the government's motion, it is premature to decide whether any particular testimony to be offered is admissible until the specific evidence to be offered is known. Similarly, the government quotes the truisms that the Court should not admit lay opinions with so little basis that they "amount[] to 'little more than choosing up sides,'" or "merely tell[] the jury 'what result to reach,'" Mot. at 4-5 (citations omitted), but offers no basis to suggest those maxims will apply here. Because no testimony is yet before the Court, the Government's argument is pure speculation.

The government suggests that opinions from attorney witnesses might be attempts at offering expert legal opinions or expert opinions on the ultimate issues for the jury. Mot. at 5-6. Again, the contention is speculative and premature until the specific testimony is known. But it is clear that attorney witnesses can testify as to factual issues, and in the course of doing so can offer lay opinions based on their factual testimony under Rule 701. "The fact that [the attorney] was a percipient witness makes a world of difference" in favor of admissibility. *Gomez*, 344

F.3d at 114; *see id.* at 114-15 (trial court abused discretion by excluding, on *per se* basis, attorney's fact testimony regarding advice he gave defendant, which would have been relevant to defendant's state of mind); *see also Park West Radiology v. CareCore Nat'l LLC*, 675 F. Supp. 2d 314, 336 (S.D.N.Y. 2009) (admitting lay opinion testimony from an attorney testifying as to a company's condition at bankruptcy "to the extent that [the testimony was] based on personal knowledge or inferences drawn in conformance with FRE 701"). Where, as here, the attorneys were direct participants in the factual events of the case, they may testify as to advice they gave the defendant, *Gomez*, 344 F.3d at 115, as well as to views of the evidence that are based on their first-hand experience with the facts. *See id.* at 113 (approving attorney's testimony where he "was a direct participant in the events at issue," and his testimony "would have been based on personal knowledge acquired before any litigation had begun); *Neutrino Dev. Corp. v. Sonosite, Inc.*, 410 F. Supp. 2d 529, 551-52 (S.D. Tex. 2006) (admitting corporate counsel's fact testimony regarding matters with which he was personally involved, including legal advice he gave the company).[23]

Moreover, Rule 704(a) expressly does away with "ultimate issue" objections for fact witnesses: "[T]estimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact." Fed. R. Evid. 704(a). Thus, a fact witness's lay opinion under Rule 701 is not objectionable because it goes to an ultimate issue for the jury, as the government suggests (Mot. at 5-6). *See United States v. Hobbs*, 190 Fed. Appx. 313, 316 (noting the Federal Rules "permit the admission of lay opinion

[23] *See also MCI*, 897 F.2d at 706 (bookkeeper's projection of profits admissible where it was predicated on her personal knowledge and perception, based on records she kept personally); *Indemnity Ins. Co. v. American Eurocopter LLC*, 227 F.R.D. 421, 424 (M.D.N.C. 2005) ("[A] person with specialized training does not testify as an expert by giving first-hand participant testimony, even though it appears to be expert testimony.").

testimony that is 'rationally based on the perception of the witness,' Fed. R. Evid. 701, even if it 'embraces an ultimate issue to be decided by the trier of fact.' Fed. R. Evid. 704."). [24]

Thus, Rule 701 does not set any general or categorical bar to lay opinion testimony from attorneys testifying as fact witnesses, as the government suggests. On the contrary, the Rule specifically permits lay opinion testimony that is grounded in witnesses' factual perceptions and is helpful to the jury in understanding the issues in dispute.

IV. Rule 701's Principles Regarding Lay Opinion Testimony Apply Evenhandedly

Finally, the principles of Rule 701 apply evenhandedly to the views and lay opinions of both government and defense witnesses. We fully anticipate that the government will try to elicit witness testimony to support its view that the statements in GSK's response letters were false or misleading, and/or were made knowingly, willfully, corruptly, or with intent to impede the FDA's inquiry. The propriety of each witness's testimony under Rule 701 must of course be assessed individually, based on the specific content, foundation, context, and purpose of the particular testimony. But Rule 701's general principles are sauce for both goose and gander. The government cannot expect to elicit witness testimony supporting the prosecution's view of these disputed issues, while precluding defense witnesses from offering contrary views.

CONCLUSION

For all of the foregoing reasons, the government's motion in limine regarding opinion testimony should be denied.

[24] Indeed, although the opinion's probative value on the core issue in dispute is what makes it both relevant under Rule 401 and helpful to the factfinder under Rule 701(b).

Respectfully Submitted,

Dated: February 25, 2011

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